

# Obesity in children and adolescents with a high risk of insulin resistance

<b>Submission date</b> 12/12/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/09/2008	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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Germany  
72076

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**

Investigation of overweight/adipose children and adolescents who face a high risk of insulin resistance: dietary intervention, exercise treatment and pre- and post-treatment status in the DISKUS study

## **Acronym**

DISKUS study

## **Study objectives**

The number of overweight children has risen staggeringly in Germany. Overweightness is associated with the metabolic syndrome and, by extension, with a high risk of cardiovascular morbidity and mortality. Up to now, attempts to treat children and adolescents have basically been limited to interventions targeting lifestyle. They have often not produced lasting effects, neither is it clear why these endeavours are shortlived. Our approach in attempting to clarify this issue is to undertake a comprehensive investigation of children and adolescents who face a high risk of the metabolic syndrome.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics approval received from the Ethics Committee of the University of Tuebingen on the 13th June 2007 (ref: 130/2007BO1).

## **Study design**

Our study is a prospective, controlled, open, non-randomised investigation.

## **Primary study design**

Interventional

## **Secondary study design**

Non randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Childhood obesity, metabolic syndrome

## **Interventions**

Schematic diagram of the trial design (intervention group):

Preliminary examination: Presentation and examination at the Hospital for Children and Adolescent Medicine (one half-day visit) and at the Department of Sports Medicine (one half-day visit), including counselling by a sports medicine clinician. Sub-group: Additional investigations in

30 randomly-chosen patients: Mental Rotations Test (MRT), eye-tracking.

Months 1 - 6: Two nutritional counselling sessions focusing on the subjects of food and beverage choices, implementation in daily life. Physical activity and exercise at home (involving family, friends, recreational centre/sports club) as recommended by the sports medicine clinician.

Month 6: First interim examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol and the physical activity log book, followed by counselling. Sub-group (n = 30): Additional investigations comprise MRT and eye-tracking.

Months 7 - 12: Nutritional counselling session and/or further sports medicine instruction if required for exercise at home (involving family, friends, recreational centre/sports club) as recommended by the sports medicine clinician.

Month 12: Second interim examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol and the physical activity log book, followed by counselling.

Months 12 - 24: Observational phase: the intervention is implemented independently by the volunteer.

Month 24: Final examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol and the physical activity log book, followed by counselling.

Schematic diagram of the trial design (control group):

Preliminary examination: Presentation and examination at the Hospital for Children and Adolescent Medicine (one half-day visit).

Months 1 - 6: One nutritional counselling session focusing on the subjects of food and beverage choices, implementation in daily life.

Month 6: First interim examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol.

Months 7 - 12: Nutritional counselling session if required.

Month 12: Second interim examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol.

Months 12 - 24: Observational phase: the intervention is implemented independently by the volunteer.

Month 24: Final examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Significant yearly changes in the BMI (Standard Deviation Score [SDS])
2. Significant yearly changes in the level of fasting insulin (HOMeostasis Model Assessment of Insulin Resistance [HOMA-IR])

Outcomes measured at baseline and months 6, 12 and 24.

## **Secondary outcome measures**

1. Improvements in physical fitness:
  - 1.1. Ventilatory threshold
  - 1.2. Period of total load
  - 1.3. Subjective fatigue
  - 1.4. Maximum heart rate

- 1.5. Watt-max test
- 1.6. Oxygen uptake
2. Lowering of the systolic/diastolic blood pressure to below the 95th centile
3. Improvements in the levels of High Density Lipoprotein (HDL) cholesterol, lowering of levels triglyceride levels
4. Reduction or reversal of pathological status of thickness and proportion of abdominal fat /skinfold thickness
5. Boost in general vigour
6. Improvement of well-being and mood, enhancement of health-related quality of life

Outcomes measured at baseline and months 6, 12 and 24.

**Overall study start date**

01/02/2008

**Completion date**

01/08/2010

## **Eligibility**

**Key inclusion criteria**

1. Overweight (Body Mass Index [BMI] greater than 90th centile) or obese (BMI greater than 97th centile)
2. Children and adolescents between the ages of 6 and 18 years
3. One or more of the following criterias:
  - 3.1. Extreme obesity (BMI greater than 99.5 centile of age- and sex-matched references)
  - 3.2. First-degree relative with type 2 diabetes/diabetes during pregnancy or two grandparents with type 2 diabetes
  - 3.3. Neonatal size either small or large for gestational age (birth weight or birth length less than 5th/greater than 95th centile)
  - 3.4. Acanthosis nigricans
  - 3.5. Polycystic ovary syndrome
  - 3.6. Children and adolescents with established glucose tolerance impairment, abnormal levels of fasting glucose, type 2 diabetes

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

Study group: n = 100; control group: n = 50

**Key exclusion criteria**

1. Type 1 diabetes
2. Eating disorder
3. Pregnancy
4. Neoplasm or severe systemic disease
5. Cardiovascular disease
6. Mental retardation
7. Mental health problem

**Date of first enrolment**

01/02/2008

**Date of final enrolment**

01/08/2010

**Locations****Countries of recruitment**

Germany

**Study participating centre**

University Children's Hospital

Tuebingen

Germany

72076

**Sponsor information****Organisation**

University Children's Hospital of Tuebingen (Germany) - Section of Pediatric Endocrinology

**Sponsor details**

c/o Michael B. Ranke, M.D.

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Tuebingen

Germany

72076

**Sponsor type**

Hospital/treatment centre

ROR

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) - an application for a Research Grant has been submitted

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration